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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,108	10/17/2003	Stephen Quirk	1443.013US2	9425

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EXAMINER	
HORLICK, KENNETH R	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/688,108	QUIRK, STEPHEN	
	Examiner	Art Unit	
	Kenneth R. Horlick	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *3-5,8-11,21-24,29-38 and 41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6,7,12-20,25-28,39 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/17/03;6/21/04* (6 pages)
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: Sequence alignments (5 pages)

1. The specification is objected to because of the following informality: the continuation information must be updated to indicate issue of the parent '552 application as U.S. Patent No. 6,696,254.

2. Applicant's election with traverse of Group I, claims 1-16, 21-32, 39, and 40, and SEQ ID NO:11-14, in the reply filed on 04/27/06 is acknowledged. The traversal is on the ground(s) that search of all groups would not be burdensome. This is not found persuasive because as pointed out in the restriction, the distinctness between nucleic acid and protein-based inventions and the different classifications does in fact support burden of search. Further, while the response traverses the sequence restriction as if it were a species election, it is noted that in fact this is a further restriction requirement and not an election of species. Due to the increasing burden of searching nucleic acid and protein sequences over the past several years, the Office has been forced to strictly impose such sequence restrictions as per its discretion.

The requirement is still deemed proper and is therefore made FINAL.

3. Including consideration of the sequence restriction, claims 3-5, 8-11, 21-24, 29-38, and 41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 04/27/06.

4. Claims 1, 2, 12-16, and 40 are objected to as containing non-elected SEQ ID NOs. Correction is required.

5. It is noted that considering the non-elected subject matter in claims 1 and 2, as well as the inherent hybridization properties recited in claims 2, 6, and 7, claims 1, 2, 6, and 7 claim the same subject matter. Further, although the preambles of claims 13 and 25 differ, the methods as defined by the recited active steps appear to be identical. Appropriate correction is required.

6. Claims 1, 2, 6, 7, 12-16, 25-28, 39, and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are drawn to subject matter encompassing the genus of nucleic acids comprising any one of SEQ ID NO:11-14. Due to the open language "comprising", the claims cover nucleic acids unlimitedly larger than the recited SEQ ID NOs but comprising them, including isolated whole Salmonella chromosomes from any and all strains comprising the sequence of said SEQ ID NOs.

The proper inquiry in the instant situation is: is there a representative number of species implicitly or explicitly disclosed, such that one of ordinary skill in the art would understand applicant to be in possession of the claimed genus?

Other relevant considerations are as follows:

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the disclosed SEQ ID NOs, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and

> reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.
>
> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

The only species of nucleic acid probes provided by Applicants useful in carrying out the claimed methods are SEQ ID NO:11-14. The specification does not describe the entire genome of any and every Salmonella strain whose DNA comprises SEQ ID NO:11-14. In addition, the specification does not describe which of the innumerable nucleic acids larger then the disclosed SEQ ID NOs will maintain useful specificity and discrimination in hybridization assays. Thus, at the time of the invention applicants were clearly not in possession of the genus recited in the claims. This rejection would be obviated by amending the claims to recite, for example, "a nucleic acid consisting of any one of SEQ ID NO:11-14", or "a nucleic acid selected from the group consisting of SEQ ID NO:11, 12, 13, and 14" (as was done in the parent application).

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by either of Accession No. AF029556 or Accession No. BB242553.

These claims are drawn to an isolated nucleic acid comprising any one of SEQ ID NO:11-14.

Accession No. AF029556 (August 2000) discloses a 944 bp nucleic acid sequence which comprises instant SEQ ID NO:11 (nucleotides 757-773), as well as instant SEQ ID NO:13 (nucleotides 719-735). See attached sequence alignments.

Accession No. BB242553 (July 2000) discloses a 242 bp nucleic acid sequence which comprises instant SEQ ID NO:14 (nucleotides 44-60). See attached sequence alignment.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12, 39, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Accession No. AF029556 or Accession No. BB242553.

These claims are drawn to a biosensor chip comprising a nucleic acid probe that can selectively hybridize to nucleic acid encoding a dGTPase from Enterobacteriaceae, or in particular a nucleic acid probe comprising any one of SEQ ID NO:11-14.

The nucleic acid sequences disclosed in these accession numbers comprise SEQ ID NO:11, 13, and 14, as described above. Further, although not explicitly taught in Accession No. AF029556, the fact that the taught *Salmonella* nucleic acid comprises instant SEQ ID NO:11 and 13 means it inherently has the property of being able to selectively hybridize to nucleic acid encoding a dGTPase from Enterobacteriaceae (i.e., from Salmonella).

These accession numbers do not disclose a biosensor chip.

One of ordinary skill in the art would have been motivated to make a biosensor chip comprising one of the noted nucleic acids because such a biosensor chip would have clearly been useful in detecting nucleic acids complementary thereto. Biosensor chips were clearly well known and common knowledge in the art at the time of the invention, and thus clearly do not bear on patentability. It would have been *prima facie*

obvious to one of ordinary skill in the art at the time of the invention to make the claimed biosensor chip.

9. Claims 13-16 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lane et al. (US 5792,854) in view of Accession No. AF029556.

These claims are drawn to methods of detecting enteric bacteria, or in particular Salmonella, using hybridization probes comprising any one of SEQ ID NO:11-14.

Lane et al. disclose the desirability of detecting Salmonella using hybridization probes (see columns 1-2).

Lane et al. do not disclose probes comprising any of SEQ ID NO:11-14.

Accession No. AF029556, as noted above, teaches a nucleic acid sequence comprising SEQ ID NO:11 and 13.

One of ordinary skill in the art would have been motivated to use the Salmonella nucleic acid sequence taught by Accession No. AF029556 in the hybridization method of Lane et al. because this would have been expected to provide an advantageous hybridization detection method to identify the well known pathogen Salmonella. It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods. It is further noted with respect to the dependent claims that amplification reactions such as polymerase chain reaction were clearly well known and common knowledge in the art at the time of the invention, and thus clearly do not bear on patentability.

10. No claims are free of the prior art. However, it is noted that nucleic acids consisting of SEQ ID NO:11-14, and methods of use thereof, represent patentable subject matter. Although the nucleic acid accession numbers noted above teach larger sequences comprising SEQ ID NO:11, 13, and 14, no prior art has been found teaching or suggesting the exact nucleic acids of any of SEQ ID NO:11-14.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R. Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kenneth R Horlick, Ph.D.
Primary Examiner
Art Unit 1637

06/08/06